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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Oshlack et al.	Confirmation No.:	6382
Serial No.:	10/706,371	Art Unit:	1617
Filed:	November 12, 2003	Examiner:	Edward J. Webman
For:	CONTROLLED RELEASE OXYCODONE COMPOSITIONS	Attorney Docket No.:	305158-999275 (6750-277-999)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

Enclosure accompanying this Information Disclosure Statement is a List of References Cited by Applicants (References **AO1-A02; B01-B04; and C01-C91).**

This application is a continuation application under 37 C.F.R. §1.53(b) or (d). Copies of the above references were submitted by Applicants and/or cited by the Examiner in prior Application Nos. 10/163,484, filed June 5, 2002; 09/933,411, filed August 20, 2001; 09/784,888, filed February 16, 2001; 09/481,909, filed January 12, 2000; 08/909,328, filed August 11, 1997; 08/618,344, filed March 19, 1996, now Patent No. 5,656,295; 08/081,302, filed June 18, 1993, now Patent No. 5,549,912; and 07/800,549, filed November 21, 1991, now Patent No. 5,266,331, to all of which this application claims priority under 35 U.S.C. §120. Hence, copies of the List of References Cited by Applicants in this Information Disclosure Statement are not being submitted pursuant to 37 C.F.R. §1.98(d). However, should the Examiner request copies of the references, Applicants would be happy to provide them.

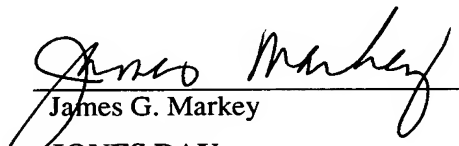
This Information Disclosure Statement supplements the Information Disclosure Statement filed on November 12, 2003.

This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R §1.97(b), but before the mailing date of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application. The Commissioner is hereby authorized to charge the $180.00 fee set forth in 37 C.F.R. §1.17(p) and any other fees that may be due in connection with this filing to Jones Day Deposit Account No. 50-3013. A copy of this sheet is enclosed.

No admission is made that the information cited in this Statement is, or is considered to be, material to patentability and no representation is made that a search has been made. 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: April 14, 2005



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Enclosures

LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATTY DOCKET NO.	APPLICATION NO.
305158-999275 (6750-277-999)	10/706,371
APPLICANT: Oshlack et al.	
FILING DATE: November 12, 2003	GROUP: 1617

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	4,235,870	11/15/1980	Leslie			
	A02	5,266,311	11/30/1993	Cerretti et al.			
	A03						
	A04						
	A05						
	A06						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	B01	DE 32 46 492	06/30/1983	Germany			X	
	B02	EP 0 249 347	12/16/1987	EPO				
	B03	CA 1,296,633	03/03/1992	Canada				
	B04	CA 1,297,025	03/10/1992	Canada				
	B05							
	B06							
	B07							
	B08							

OTHER REFERENCES *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	C01	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1987; (7th ed.):3-172.
	C02	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1988; (8th ed.):3-179
	C03	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1989; (9th ed.):3-199.
	C04	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1990; (10th ed.):3-200.
	C05	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1991; (11th ed.):3-200.
	C06	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1992; (12th ed.):3-197.
	C07	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1993; (13th ed.):3-198.
	C08	April 11, 2004 Amicus Curae Brief of Guilford Pharmaceuticals in Support of Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company and EuroCeltique S.A. in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs/ Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaimant-Appellee), Endo Pharmaceuticals Holdings Inc. (Defendant-Appellee)*, United States Court of Appeals for the Federal Circuit, Appeals Nos. 04-1189, -1226
	C09	April 2, 2004 Corrected Brief of Plaintiffs-Appellants in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs/ Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaimant-Cross Appellant), Endo*

		Pharmaceuticals Holdings Inc. (Defendant-Cross Appellant), United States Court of Appeals for the Federal Circuit, Appeals Nos. 04-1189, -1226
	C10	August 3, 2001 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 80 mg, from Teva Pharmaceuticals USA to Euro-Celtique S.A.
	C11	Black: A rational approach to cancer pain management. J. of Family Practice. 1989;28(3):267-8.
	C12	Chang et al. Sustained drug release from tablets and particles through coating.
	C13	Codeine. *Available at* http://esc.syrres.com/interkow/webprop.exe.
	C14	Codeine. Clark's Isolation and Identification of Drugs. 1986;490-1.
	C15	Codeine. The Merck Index 1989;(11th ed.):384-5.
	C16	Conrad et al. Sustained drug release from tablets and particles through coating *in* Pharmaceutical Dosage Forms-Tablets (Lieberman et al., eds). 1982. 3(4):149-221.
	C17	Conrad et al. Sustained drug release from tablets and particles through coating *in* Pharmaceutical Dosage Forms-Tablets (Lieberman et al., eds). 1982. 3(4):149-221.
	C18	Endo's February 17, 2004 Memorandum in support of its Motion for Relief from Order with respect to Infringement in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs and Counterclaim Defendants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings Inc. (Defendant)* Civil Action Nos. 00-CV 8029 (SHS); 01-CV 2109 (SHS) and 01-CV 8177(SHS)
	C19	Endo's March 19, 2004 Reply Memorandum in support of its Motion for Relief from Order with respect to Infringement in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs and Counterclaim Defendants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings Inc. (Defendant)* Civil Action Nos. 00-CV 8029 (SHS); 01-CV 2109 (SHS) and 01-CV 8177(SHS)
	C20	Endo's Initial Post-Trial Brief dated 7/25/2003 *in* Purdue Pharma L.P. et al. v. Endo Pharmaceuticals Inc. et al. v. Euroceltique S.A., 00 Civ.-8029 (SHS); 01 Civ.-2109 (SHS); and 01-Civ.-8117 (SHS).
	C21	Endo's Post-Trial Proposed Findings of Fact dated 7/25/2003 *in* Purdue Pharma L.P. et al. v. Endo Pharmaceuticals Inc. et al. v. Euroceltique S.A., 00 Civ.-8029 (SHS); 01 Civ.-2109 (SHS); and 01-Civ.-8117 (SHS).
	C22	Endo's Post-Trial Proposed Conclusions of Law dated 7/25/2003 *in* Purdue Pharma L.P. et al. v. Endo Pharmaceuticals Inc. et al. v. Euroceltique S.A., 00 Civ.-8029 (SHS); 01 Civ.-2109 (SHS); and 01-Civ.-8117 (SHS).
	C23	Endo's Post-Trial Response Brief dated 8/8/2003 *in* Purdue Pharma L.P. et al. v. Endo Pharmaceuticals Inc. et al. v. Euroceltique S.A., 00 Civ.-8029 (SHS); 01 Civ.-2109 (SHS); and 01-Civ.-8117 (SHS).
	C24	February 25, 2002 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 80 mg, from Impax Laboratories, Inc. to Purdue Pharma L.P. and The Purdue Frederick Company
	C25	February 25, 2003 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 10, 20 and 40 mg, from Teva Pharmaceuticals USA to Purdue Pharma L.P., The P.F. Laboratories, Inc. and Euro-Celtique S.A.
	C26	February 9, 2001 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 10 and 20 mg, from Endo Pharmaceuticals, Inc. to Euro-Celtique S.A., The Purdue Pharma Company, Purdue Pharma L.P., Steinberg & Raskin, Davidson & Davidson, The Purdue Frederick Company and The P.F. Laboratories, Inc.
	C27	Foldes. Role of oral and parenteral drugs in the management of intractable pain. Pain. 1988;9:286-9.
	C28	Gibaldi. Prolonged-release medication. Biopharm. and Clin. Pharmcokinetics. 1991;(4th ed.):124-45.
	C29	Gibaldi. Prolonged-release medication. Biopharmaceutics and Clinical Phamakokinetics. 1984 (3rd ed);27:113-130.
	C30	Guay et al. Pharmacokinetics of codeine after single- and multiple-oral-dose administration to normal volunteers. J Clin Pharmacol. 1987 Dec;27(12):983-7.
	C31	Hydromorphone. *Available at* http://esc.syrres.com/interkow/webprop.exe.
	C32	Hydromorphone. Clarke's Isolation and Identification of Drugs. 1986; 667-8.
	C33	Hydromorphone. The Merck Index. 1989;(11th ed.):762.
	C34	IMS Study (D18).
	C35	Inturrisi, Role of opioid analgesics. Am J Med. 1984 Sep 10;77(3A):27-37.
	C36	Inturrisi. Management of cancer pain pharmacology and principles of management. Cancer. 1989 June;63:2308-20.
	C37	July 31, 2001 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 80 mg, from Endo Pharmaceuticals, Inc. to Euro-Celtique S.A., The Purdue Pharma Company, Purdue Pharma L.P., Steinberg & Raskin, Davidson & Davidson, The Purdue Frederick Company and The P.F. Laboratories, Inc.
	C38	June 16, 2004 Reply Brief of Plaintiffs-Appellants in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs/ Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaimant- Cross Appellant), Endo Pharmaceuticals Holdings Inc. (Defendant- Cross Appellant)*, United States Court of Appeals for the Federal Circuit, Appeals Nos. 04-1189, -1226, -1347, -1357
	C39	June 30, 2004 Reply Brief of Defendants/Cross-Appellants in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs/ Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaimant- Cross Appellant), Endo Pharmaceuticals Holdings Inc. (Defendant- Cross Appellant)*, United States Court of Appeals for the Federal Circuit,

		Appeals Nos. 04-1189, -1347, -1357
	C40	Kaiko, Robert, Dr., Declaration dated 3/9/1993 *in* United States Patent Application No. 07/800,549, filed 11/27/1991.
	C41	Kalso et al. Morphine and oxycodone hydrochloride in the management of cancer pain. Clin Pharmacol Ther. 1990 May;47(5):639-46.
	C42	Khojasteh et al. Controlled-release oral morphine sulfate in the treatment of cancer pain with pharmacokinetic correlation. J Clin Oncol. 1987 Jun;5(6):956-61.
	C43	Lee et al. Methods to achieve sustained drug delivery. The physical approach: Oral and parenteral dosage forms. Sustained and Controlled Release Drug Delivery Systems. 1978;(3)123-209.
	C44	Lee et al. Methods to achieve sustained drug delivery. The physical approach: Oral and parenteral dosage forms. Sustained and Controlled Release Drug Delivery Systems. 1978;(3)123-204.
	C45	Leow. The clinical pharmacology of oxycodone. A thesis submitted for the degree of Doctor of Philosophy of the University of Queensland. 1993.
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	C47	Maruta et al. Problems with the use of oxycodone compound in patients with chronic pain. Pain. 1981 Dec;11(3):389-96.
	C48	May 12, 2004 Brief of Defendants/Cross-Appellants in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs/ Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaimant- Cross Appellant), Endo Pharmaceuticals Holdings Inc. (Defendant- Cross Appellant)*, United States Court of Appeals for the Federal Circuit, Appeals Nos.04-1189, -1226, -1347, -1357
	C49	McKay. Pain management for urological malignancies. Urol Int. 1991;46(3):252-8. Review.
	C50	Mikus. Polymorphic metabolism of opioid narcotic drugs: Possible clinical implications. Annals Acad. of Medicine. 1991 Jan;20(1):10-12.
	C51	Morphine sulfate sustained release. Compendium of Pharmaceutical and Specialties. 1988;572-3.
	C52	Morphine sulfate. *Available at* http://esc.syrres.com/interkow/webprop.exe.
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	C54	Morphine. Clarke's Isolation and Identification of Drugs. 1986;790-1.
	C55	Morphine. The Merck Index. 1989;(11th ed.):988-9.
	C56	Muhtadi et al. Codeine phosphate. Analytical Profiles of Drug Substances. 1981;(10):93-138.
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	C58	Nichols et al. Oxycodone injection: Pharmacokinetics. Abstracts 10th World Congress on Pain. 2002 Aug;59 (191-P87) *and* Final Study Report.
	C59	November 8, 2001 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 160 mg, from Teva Pharmaceuticals USA to Purdue Pharma L.P.
	C60	Oral oxycodone: new preparation. No better than oral morphine. Prescrire Int. 2003 Jun;12(65):83-4.
	C61	Oshlack. Internal memorandum regarding R&D. 1983 Aug.
	C62	Oshlack. Notes on Example 2 of D1. The Purdue Frederick Research Center. 1982.
	C63	Oxycodone HCI trihydrate. Compendium of Pharmaceuticals and Specialties. 1988;879.
	C64	Oxycodone. *Available at* http://esc.syrres.com/interkow/webprop.exe
	C65	Oxycodone. Clark's isolation of Drugs. 1986; 841.
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	C67	Parab et al. Pharmacokinetics of hydromorphone after intravenous, peroral and rectal administration to human subjects. Biopharm Drug Dispos. 1988 Mar-Apr;9(2):187-99.
	C68	Pöyhia et al. The pharmacokinetics and metabolism of oxycodone after intramuscular and oral administration to healthy subjects. Br J Clin Pharmacol. 1992 Jun;33(6):617-21.
	C69	Product Information OxyContin (D17c).
	C70	Product Information. 1990; 710-3 (D17a).
	C71	Product Information. 2001 (D17b).
	C72	*Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs and Counterclaim Defendants) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings Inc. (Defendant) v. EuroCeltique S.A. (Counterclaim Defendant)* 2004 WL 26523 (S.D.N.Y. Jan. 5, 2004), 70 U.S.P.Q.2d 1185
	C73	Purdue's March 12, 2004 Opposition to Endo's Motion for Relief from Order with respect to Infringement in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs and Counterclaim Defendants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings Inc. (Defendant)* Civil Action Nos. 00-Civ 8029 (SHS); 01-Civ 2109 (SHS) and 01-Civ 8177(SHS)

List of References of Application No. 10/706,371

	C74	Purdue's Opening Brief After Trial dated 7/25/2003 *in* Purdue Pharma L.P. et al. v. Endo Pharmaceuticals Inc. et al. v. Euroceltique S.A., 00 Civ.-8029 (SHS); 01 Civ.-2109 (SHS); and 01-Civ.-8117 (SHS).
	C75	Purdue's Proposed Findings of Fact and Conclusions of Law After Trial dated 7/25/2003 *in* Purdue Pharma L.P. et al. v. Endo Pharmaceuticals Inc. et al. v. Euroceltique S.A., 00 Civ.-8029 (SHS); 01 Civ.-2109 (SHS); and 01-Civ.-8117 (SHS).
	C76	Purdue's Reply Brief After Trial dated 8/8/2003 *in* Purdue Pharma L.P. et al. v. Endo Pharmaceuticals Inc. et al. v. Euroceltique S.A., 00 Civ.-8029 (SHS); 01 Civ.-2109 (SHS); and 01-Civ.-8117 (SHS).
	C77	Ripamonti; Traitement de la douleur et soins palliatifs pour les malades atteints de cancer avancé. Doul. et Analg. 1990;3:75-81 (in French, w/ English abstract).
	C78	Rischitelli et al. Safety and efficacy of controlled-release oxycodone: a systematic literature review. Pharmacotherapy. 2002 Jul;22(7):898-904. Review.
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	C80	Roy et al. Solubility and related physicochemical properties of narcotic analgesics. Pharm Res. 1988 Sep;5(9):580-6.
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	C82	Schneider. The pharmacology of oxycodone and morphine. A thesis submitted for the degree of Doctor of Philosophy in Pharmacy of The University of Queensland. 1989.
	C83	September 24, 2002 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 10 and 20 mg, from Impax Laboratories, Inc. to Purdue Pharma L.P. and The Purdue Frederick Company
	C84	September 4, 2002 Resubmission of August 19, 2002 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 40 mg, from Impax Laboratories, Inc. to Purdue Pharma L.P. and The Purdue Frederick Company
	C85	September 8, 2000 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 40 mg, from Endo Pharmaceuticals, Inc. to Euro-Celtique S.A., The Purdue Pharma Company, Purdue Pharma L.P., Steinberg & Raskin, Davidson & Davidson, The Purdue Frederick Company and The P.F. Laboratories, Inc.
	C86	Silber et al. Utilizing pharmacokinetic principles in the design of controlled or sustained release formulations. Pharmcodynamics Dept., Med. Res. Div. Am. Cyanamid Co.;1-33.
	C87	Stambaugh et al. Double-blind, randomized comparison of the analgesic and pharmacokinetic profiles of controlled- and immediate-release oral oxycodone in cancer pain patients. J Clin Pharmacol. 2001 May;41(5):500-6.
	C88	Thomas. Endone. Australia Prescription Products Guide. 1989;1(A-H):646.
	C89	Thomas. Endone. Australia Prescription Products Guide. 1990;1(A-H):676.
	C90	Urquhart. Performance requirements for controlled-release dosage forms: Therapeutic and pharmacological perspectives. Controlled-Release Pharmaceuticals. 1981;1-48.
	C91	Vallner et al. Pharmacokinetics and bioavailability of hydromorphone following intravenous and oral administration to human subjects. J Clin Pharmacol. 1981 Apr;21(4):152-6.

EXAMINER	**DATE CONSIDERED**

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with **MPEP 609**; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.